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Patent Docket P1467R2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Camellia W. Adams et al. Serial No.: 09/602,812 Filed: June 23, 2000 For: Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies	Group Art Unit: 1644 Examiner: not yet assigned CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on January 24, 2001 <i>Ann Savelli</i> Ann Savelli
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

- ☒ **37 CFR §1.97(b)**
- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); **or**
 - within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, **or**
 - before the mailing of the first Office action on the merits; **or**
 - before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.
- ☐ **37 CFR §1.97(c)**
- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below.
- ☐ **37 CFR §1.97(d)**
- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37

CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☐ not given
- ☐ given for each listed item
- ☒ given for only non-English language listed item(s) [Required]

An English language translation is provided for item 166.
English language abstracts are provided for items 168-173
English language abstracts and claims are provided for items 167 and 174

- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

By: _____

Wendy Lee

Reg. No. 40,378

Telephone No. (650) 225-1994

Date: January 23, 2001



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PATENT TRADEMARK OFFICE

FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1467R2	Serial No. 09/602,812		
				Applicant Adams et al.			
				Filing Date 23 Jun 2000			
				Group To Be Assigned			
U.S. PATENT DOCUMENTS							
Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	116	4,753,894	28.06.88	Frankel et al.			
	117	4,935,341	19.06.90	Bargmann et al.			
	118	4,943,533	24.07.90	Mendelsohn et al.			
	119	4,975,278	04.12.90	Senter et al.			
	120	5,169,774	08.12.92	Frankel et al.			
	121	5,288,477	22.02.94	Bacus, S.			
	122	5,359,046	25.10.94	Capon et al.			
	123	5,367,060	22.11.94	Vandlen et al.			
	124	5,401,638	28.03.95	Carney et al.			
	125	5,464,751	07.11.95	Greene et al.			
	126	5,578,482	26.11.96	Lippman et al.			
	127	5,604,107	18.02.97	Carney et al.			
	128	5,663,144	02.09.97	Greene et al.			
	129	5,705,157	06.01.98	Greene, M. L.			
	130	5,720,937	24.02.98	Hudziak et al.			
	131	5,720,954	24.02.98	Hudziak et al.			
	132	5,725,856	10.03.98	Hudziak et al.			
	133	5,726,023	10.03.98	Cheever et al.			
	134	5,728,687	17.03.98	Bissery, M.			
	135	5,747,261	05.05.98	King et al.			
	136	5,770,195	23.06.98	Hudziak et al.			
	137	5,772,997	30.06.98	Hudziak et al.			
	138	5,776,427	07.07.98	Thorpe et al.			
	139	5,801,005	01.09.98	Cheever et al.			
	140	5,834,229	10.11.98	Vandlen et al.			
	141	5,837,243	17.11.98	Deo et al.			
	142	5,837,523	17.11.98	Greene et al.			
	143	5,840,525	24.11.98	Vandlen et al.			
	144	5,846,538	08.12.98	Cheever et al.			
	145	5,856,110	05.01.99	Vandlen et al.			
	146	5,859,206	12.01.99	Vandlen et al.			
	147	5,869,445	09.02.99	Cheever et al.			
	148	5,876,712	02.03.99	Cheever et al.			
	149	5,877,305	02.03.99	Huston et al.			
	150	5,908,835	01.06.99	Bissery, M.			
	151	5,910,486	08.01.99	Curiel et al.			
Examiner					Date Considered		

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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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		Filing Date 23 Jun 2000	Group To Be Assigned

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	152	5,922,845	13.07.99	Deo et al.			
	153	5,939,531	17.08.99	Wels et al.			
	154	5,968,511	19.10.99	Akita et al.			
	155	5,977,322	02.11.99	Marks et al.			
	156	5,985,553	16.11.99	King et al.			
	157	6,015,567	18.01.00	Hudziak et al.			
	158	6,028,059	22.02.00	Curriel et al.			
	159	6,054,297	25.04.00	Carter et al.			
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	161	6,096,873	01.08.00	Schaefer et al.			
	162	6,123,939	26.09.00	Shawver et al.			
	163	6,165,464	26.12.00	Hudziak et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	164	0,616,812 A1	28.09.94	EPO				
	165	711,565	26.08.98	EPO				
	166	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)				
	167	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	168	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	169	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	170	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	171	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	172	5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	173	7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	174	95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	175	WO 00/61185	19.10.00	PCT				
	176	WO 89/06692	27.07.89	PCT				
	177	WO 92/10573	25.06.92	PCT				
	178	WO 93/12220	24.06.93	PCT				
	179	WO 93/21232	28.10.93	PCT				
	180	WO 93/21319	28.10.93	PCT				
	181	WO 94/28127	08.12.94	PCT				
	✓ 182	WO 95/16051	15.06.95	PCT				
	183	WO 95/17507	29.06.95	PCT				
	184	WO 95/28485	26.10.95	PCT				

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FOREIGN PATENT DOCUMENTS								
Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
	185	WO 96/18409	20.06.96	PCT				
	186	WO 97/04801	13.02.97	PCT				
	187	WO 97/20858	12.06.97	PCT				
	188	WO 97/27848	07.08.97	PCT				
	189	WO 97/38731	23.10.97	PCT				
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	191	WO 99/31140	24.06.99	PCT				

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192	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (Mab) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)
193	Baselga et al., "HER2 overexpression and paclitaxel sensitivity in breast cancer: therapeutic implications" <u>Oncology</u> 11(3 Suppl 2):43-48 (Mar 1997)
194	Baselga et al., "Monoclonal antibodies directed against growth factor receptors enhance the efficacy of chemotherapeutic agents" <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)
195	Baselga et al., "Recombinant Humanized Anti-HER2 Antibody (Herceptin) Enhances the Antitumor Activity of Paclitaxel and Doxorubicin against HER2/neu Overexpressing Human Breast Cancer Xenografts" <u>Cancer Research</u> 58:2825-2831 (July 1998)
196	De Santes et al., "Radiolabeled Antibody Targeting of the HER-2/neu Oncoprotein" <u>Cancer Research</u> 52:1916-1923 (1992)
197	DiFiore et al., "erbB-2 is a potent oncogene when overexpressed in NIH/3T3 cells" <u>Science</u> 237(4811):178-182 (Jul 10, 1987)
198	Drebin et al., "Inhibition of tumor growth by a monoclonal antibody reactive with an oncogene-encoded tumor antigen" <u>Proc. Natl. Acad. Sci.</u> 83:9129-9133 (1986)
199	Drebin et al., "Monoclonal Antibodies Specific for the neu Oncogene Product Directly Mediate Anti-tumor Effects In Vivo" <u>Oncogene</u> 2(4):387-394 (1988)
200	Fleiss, JL <u>Statistical Methods for Rates and Proportions</u> , 2nd edition, New York, NY:Wiley pps. 13-17 (1981)
201	Gemzar (gemcitabine HCL), "Product Information - PDR" (2000)
202	Green et al., "Preclinical Evaluation of WR-151327: An Orally Active Chemotherapy Protector" <u>Cancer Research</u> 54(3):738-741 (Feb 1, 1994)
203	Guy et al., "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease" <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)
204	Hynes and Stern, "The biology of erbB-2/neu/HER-2 and its role in cancer" <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)
205	Ilgen et al., "Characterization of anti-HER/2 antibodies which inhibit the growth of breast tumor cells in vitro" <u>Proceedings of the American Association for Cancer Research</u> (abstract #3209) 37:470 (Mar 1996)
206	Masuko et al., "A murine Monoclonal Antibody That Recognizes an Extracellular Domain of the Human c-erbB-2 Protooncogene Product" <u>Jpn J. Cancer Res.</u> 80:10-14 (January 1989)

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U.S. Dept. of Commerce
Patent and Trademark Office

Atty Docket No.
P1467B2

Serial No.
09/602,812

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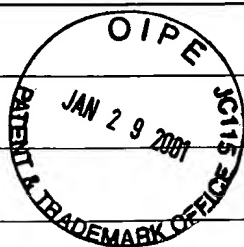
Applicant
Adams et al.

Filing Date
23 Jun 2000

Group
To Be Assigned

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

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| 207 | Mendelsohn et al., "Receptor blockade and chemotherapy: a new approach to combination cancer therapy" <u>Annals of Oncology</u> (abstract #040) 7(Suppl. 1):22 (1996) |
| 208 | Norton, L, "Evolving concepts in the systemic drug therapy of breast cancer" <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997) |
| 209 | Pegram et al., "Inhibitory effects of combinations of HER-2/neu antibody and chemotherapeutic agents used for treatment of human breast cancers" <u>Oncogene</u> 18:2241-2251 (1999) |
| 210 | Raefsky et al., "Phase II Trial of Docetaxel and Herceptin as First- or Second-Line Chemotherapy for Women with Metastatic Breast Cancer Whose Tumors Overexpress HER2" <u>Proceedings of ASCO (Abstract #523)</u> 18:137a (1999) |
| 211 | Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995) |
| 212 | Rodeck et al., "Interactions between growth factor receptors and corresponding monoclonal antibodies in human tumors" <u>J. Cellular Biochem.</u> 35(4):315-320 (1987) |
| 213 | Schlom, J., "Monoclonal Antibodies: They're More and Less Than You Think" <u>Molecular Foundations of Oncology</u> , Broder, S. ed., Baltimore, MD:Williams & Wilkins, Chapter 6, pps. 95-134 (1991) |
| 214 | Selfert et al., "Dexrazoxane in the prevention of doxorubicin-induced cardiotoxicity" <u>Annals of Pharmacotherapy</u> 28(9):1063-1072 (Sep 1994) |
| 215 | Singal and Iliskovic, "Doxorubicin-induced cardiomyopathy" <u>New England J. of Medicine</u> 339(13):900-905 (Sep 24, 1998) |
| 216 | Singal et al., "Combination therapy with probucol prevents adriamycin-induced cardiomyopathy" <u>Journal of Molecular & Cellular Cardiology</u> 27(4):1055-1063 (Apr 1995) |
| 217 | Sliwkowski et al., "A humanized monoclonal antibody for the treatment of HER2 overexpressing breast cancer" <u>Proceedings of the American Association for Cancer Research</u> 37:625-626 (Mar 1996) |
| 218 | Zhang et al., "Shared antigenic epitopes and pathobiological functions of anti-p185 ^{HER2/neu} monoclonal antibodies" <u>Experimental and Molecular Pathology</u> 67:15-25 (1999) |



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